E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0005; FRL-10908-01-OCSPP]

Fomesafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fomesafen in or on Vegetable, bulb, group 3-07; Vegetable, cucurbit, group 9; Vegetable, fruiting, group 8-10; and Vegetable, legume, forage and hay, except soybean, subgroup 7-22A. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0005, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration

Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0005 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing

Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0005, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of April 28, 2022 (87 FR 25178) (FRL-9410-12-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8957) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.433 be amended by establishing tolerances for residues of fomesafen, 5–2-chloro-4-(trifluoromethyl)phenoxy-*N*-(methylsulfonyl)-2-nitrobenzamide in or on the raw agricultural

commodities Vegetable, bulb, group 3-07 at 0.02 parts per million (ppm); Vegetable, cucurbit, group 9 at 0.025 ppm; Vegetable, foliage of legume, except soybean, subgroup 7A at 0.05 ppm; and Vegetable, fruiting, group 8-10 at 0.025 ppm.

The petition also proposed to remove established tolerances for residues of fomesafen in or on the following: Cantaloupe at 0.025 ppm; Cucumber at 0.025 ppm; Pepper, bell at 0.025 ppm; Pepper, non-bell at 0.025 ppm; Pumpkin at 0.025 ppm; Squash, summer at 0.025 ppm; Squash, winter at 0.025 ppm; Tomato at 0.025 ppm; and Watermelon at 0.025 ppm.

That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov*. One comment was submitted in response to this petition. EPA's response to this comment can be found in Unit VI.D. of this publication.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying some of the requested tolerances and one of the tolerance definitions. For details, see Unit VI.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action.

EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fomesafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fomesafen follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for fomesafen, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fomesafen and established tolerances for residues of that chemical. EPA is incorporating previously published sections of that rulemaking that remains unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by fomesafen, can be found in the document titled "Fomesafen. Human Health Risk Assessment for the Petition to Establish Permanent Tolerances and Associated Registrations for Bulb Vegetable (Group 3-07) and Vegetable, Foliage of Legume Except Soybean (Subgroup 7A) and for Proposed Crop Group Conversions and Expansions for Vegetable, Cucurbit (Group 9) and Vegetable, Fruiting (Group 8-10)." (hereafter, the Fomesafen Human Health Assessment) which is available in the docket for this action at *https://www.regulations.gov*.

Toxicological profile. Fomesafen is an herbicide that is absorbed by leaves and roots and inhibits potato polyphenol oxidase (PPO), leading to irreversible cell membrane damage. PPO inhibits a step in the protoporphyrin synthesis pathway and is a precursor to both chlorophyll and hemoglobin synthesis. The toxicological database for fomesafen is complete. The primary target

organ of fomesafen is the liver. Generally, in rats, after subchronic and chronic exposure, liver histopathology (hyalinization of hepatocytes, necrosis, etc.) provided the most sensitive toxicological endpoint. In mice, liver tumors were observed after chronic exposure, and liver carcinogenicity has been established by a peroxisome proliferator-activated receptor (PPAR)-alpha mode of action. Decreased motor activity was observed at doses above those causing liver toxicity. Post-implantation loss was noted in the rat developmental study, but no quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats in developmental studies or in the 2-generation reproduction study. Fomesafen can result in suppression of anti-sheep red blood cell (SRBC) immunoglobulin M response; however, this immunotoxic potential was noted only at high doses. In a metabolism study in rats, fomesafen was readily absorbed in male and female rats after oral dosing. The sex difference was not evident at higher doses, where urine was the main route of excretion after a single oral dose of 500 mg/kg. However, a marked sex difference in disposition was observed at low doses, with females excreting a higher percentage compared to males.

Carcinogenicity was not observed in the rat chronic toxicity/carcinogenicity study. Liver tumors were produced in the mouse carcinogenicity study; however, the Agency determined that fomesafen should be classified as "Not Likely to be Carcinogenic to Humans." This decision was based on the weight-of-evidence (WOE) which supports activation of peroxisome proliferator-activated receptor alpha (PPARα) as the mode of action for fomesafen-induced hepatocarcinogenesis in mice.

Toxicological points of departure/ Levels of concern. The toxicological endpoints for fomesafen have changed since the last rulemaking and have been updated in accordance with current hazard evaluation practices. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Section 4.5.3. of the Fomesafen Human Health Assessment.

Exposure assessment. Much of the exposure assessment remains the same since the

rulemaking that published on February 7, 2018 (83 FR 5312) (FRL-9972-66), although the new exposure assessment incorporates additional dietary exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of EPA's approach to and assumptions for the exposure assessment, see Unit III.C in the February 7, 2018, rulemaking.

EPA conducted unrefined acute and chronic dietary (food and drinking water) exposure and risk assessments using the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCID, ver. 4.02) which incorporates food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2005-2010). The acute and chronic dietary assessments used tolerance-level residues, 100 percent crop treated (PCT) and default processing factors.

Drinking water and non-occupational exposures. The estimated drinking water concentrations (EDWCs) have been updated since the 2018 rulemaking. The Agency used EDWCs of 154 parts per billion for the acute assessment and 118 ppb for the chronic assessment.

There are no proposed or registered residential uses of fomesafen at this time; therefore, a quantitative residential assessment was not conducted.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fomesafen and any other substances. For the purposes of this action, therefore, EPA has not assumed that fomesafen has a common mechanism of toxicity with other substances.

IV. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an

additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat fetuses to *in utero* exposure to fomesafen. Post-implantation loss was noted in the rat developmental study, but no quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats in developmental studies or in the 2-generation reproduction study. As the etiology of the post-implantation loss is unknown, it is considered to be both a maternal and fetal endpoint and not indicative of increased susceptibility.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the Food Quality Protection Act Safety Factor were reduced to 1X. That decision is based on the following findings:

i. The toxicology database for fomesafen is complete and sufficient for assessing potential susceptibility to infants and children.

ii. The potential of neurotoxicity (decreased motor activity) was observed in the acute neurotoxicity study in the rat. However, there is a low degree of concern for the potential neurotoxic effects of fomesafen since (1) clear no observed adverse effect levels (NOAELs) were identified for the neurotoxic effects; and (2) the endpoints chosen for risk assessment are protective of any potential neurotoxicity.

iii. There is no evidence of increased susceptibility after exposure to fomesafen. Post-implantation loss was observed in the rat developmental toxicity study. However, as the etiology of the effect is unknown, it is considered to be both a maternal and fetal effect.

iv. There are no residential uses for fomesafen, and the dietary assessment is based on high-end exposure assumptions including 100 PCT, tolerance level residues, and high-end estimates derived from ground drinking water modeling estimates. These exposure assessments are not likely to underestimate the resulting estimates of risk from exposure to fomesafen.

V. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD: they are 2.8% of the aPAD for all infants less than 1 year old, the population group with the highest exposure estimate. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD: they are 18% of the cPAD for all infants less than 1 year old, which is the population subgroup with the highest exposure estimate.

Because there are no proposed or registered residential uses of fomesafen, the acute and chronic aggregate risks are the same as the dietary (food and drinking water) risks and are not of concern. Finally, because fomesafen is classified as "Not Likely to be Carcinogenic to Humans" due to an absence of carcinogenicity in the available studies, EPA concludes that aggregate exposure to fomesafen will not pose a cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fomesafen residues.

VI. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the

February 7, 2018, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are currently no established Codex MRLs for the proposed new uses of fomesafen.

C. Revisions to Tolerances

The petitioner requested tolerances for the Vegetable, foliage of legume, except soybean, subgroup 7A, but EPA is establishing the tolerance for the new crop subgroup Vegetable, legume, forage and hay, except soybeans, subgroup 7-22A. As noted in EPA's regulations, once a revised crop group is established, EPA no longer establishes crop groups under the pre-existing crop group. *See* 40 CFR 180.40(j)(4). EPA updated subgroup 7A in its final rule dated September 21, 2022. *See* Pesticides; Expansion of Crop Grouping Program VI (87 FR 57627) (FRL-5031-13-OCSPP). Additionally, the petitioned-for tolerances of 0.025 ppm for the Vegetable, cucurbit, group 9 and Vegetable, fruiting, group 8-10 are being established at 0.03 ppm to be consistent with Agency rounding practice.

D. Response to Comments

One comment was received in response to the Notice of Filing. The commenter stated in part that they were "against approval of any of the below applications for further pollution of the air water soil of this earth" and that the Agency should "shut down these dirty rotten businesses. now." Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerances are safe. Upon consideration of the validity, completeness, and reliability of the available data as well as

other factors the FFDCA requires EPA to consider, EPA has determined that the fomesafen tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

VII. Conclusion

Therefore, tolerances are established for residues of fomesafen in or on the Vegetable, bulb, group 3-07 at 0.02 ppm; Vegetable, cucurbit, group 9 at 0.03 ppm; Vegetable, fruiting, group 8-10 at 0.03 ppm; and Vegetable, legume, forage and hay, except soybean, subgroup 7-22A at 0.05 ppm.

Additionally, the established tolerances on Cantaloupe; Cucumber; Pepper, bell; Pepper, non-bell; Pumpkin; Squash, summer; Squash, winter; Tomato; and Watermelon are removed as unnecessary.

VIII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

IX. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: May 4, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.433 to read as follows:

§ 180.433 Fomesafen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fomesafen, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified in the following table 1 to this paragraph (a) is to be determined by measuring only fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
Berry, low growing, subgroup 13-07G, except cranberry	0.02
Cotton, gin byproducts	0.025
Cotton, undelinted seed	0.025
Vegetable, bulb, group 3-07	0.02
Vegetable, cucurbit, group 9	0.03
Vegetable, fruiting, group 8-10	0.03
Vegetable, legume, forage and hay, except soybean, subgroup 7-22A	0.05
Vegetable, legume, group 6	0.05
Vegetable, tuberous and corm, subgroup 1C	0.025

(b) – (d) [Reserved]

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